# In the United States Court of Federal Claims

### OFFICE OF SPECIAL MASTERS No. 20-1864V

David J. Carney, Green & Schafle LLC, Philadelphia, PA, for Petitioner.

Mary E. Holmes, U.S. Department of Justice, Washington, DC, for Respondent.

# ENTITLEMENT DECISION<sup>1</sup>

On December 14, 2020, Barbara Brewer filed a petition seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program"). Petitioner alleges she suffered a right-side Shoulder Injury Related to Vaccine Administration ("SIRVA") following receipt of an influenza ("flu") vaccine on September 10, 2020. Petition (ECF No. 1) ("Pet.") at 1.

Respondent has moved to dismiss the claim, and the parties have offered briefs in support of their respective positions. Respondent's Motion, dated May 1, 2023 (ECF No. 40) ("Mot."); Petitioner's Opposition, dated May 31, 2023 (ECF No. 41) ("Opp."); Respondent's Reply, dated June 14, 2023 (ECF No. 43) ("Reply"). Based on a review of those briefs, the medical record, and

<sup>&</sup>lt;sup>1</sup> Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id*.

<sup>&</sup>lt;sup>2</sup> The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

expert submissions, I find Respondent's motion well-taken and therefore grant it, for the reasons set forth below.

### I. Factual Background

On September 10, 2020, Petitioner (who was 70 years old at the time) received the flu vaccine at a pharmacy. See Exhibit 1 at 4.3 The relevant record indicates the vaccine was administered in her left shoulder, although the accuracy of this representation is disputed. The medical records also reveal that Petitioner had experienced preexisting right and left shoulder pain, but she maintains that any right-side concerns did not exist at the time of vaccination, and that her post-vaccination condition is distinguishable. See generally Ex. 8 (Petitioner's Supp. Affidavit). Also significant is pre-vaccination treatment evidence of prior falls. See, e.g., Ex. 4 at 4 (citing January 2015 record referencing Petitioner's frequent complaints about her knees and legs feeling weak, along with a feeling that she might fall), 125 (citing June 2018 record which indicates Petitioner tripped at her daughter's house, and that her right knee constantly aches and throbs), and 131 (citing August 2018 record which noted that Petitioner slipped and fell onto her right knee and twisted her left knee).

Later that same day, Ms. Brewer presented to Russellville Hospital emergency room in Russellville, Alabama, for an evaluation of a non-displaced, comminuted (meaning producing fragments) closed fracture of the shaft of the right humerus. Ex. 3 at 4–12. The emergency room physician noted that Petitioner reported her injury had occurred as a result of a fall at home. *Id.* at 4 ("[t]he problem was [injury] *sustained at home, resulted from a fall ... [t]he symptoms/episode began/occurred just prior to arrival* [at the ER]") (emphasis added). Petitioner specifically reported to the triage nurse that she had "right shoulder pain, denies injury, states she just heard a pop." *Id.* at 9. Petitioner's x-rays of her right extremity displayed an impacted transverse fracture of the neck of the humerus and an avulsion fracture of the lateral cortex of the greater tuberosity. *Id.* at 6. Petitioner was administered morphine, provided a sling, and discharged home with prescriptions for anti-inflammatories and a muscle relaxant. *Id.* at 5.

Petitioner vigorously denies the accuracy of this ER record—particularly its memorialization of a fall at home. She maintains instead that the day she received the vaccine, she heard a pop in her right shoulder and immediately her arm felt painful and heavy, requiring her to use her left hand to support her right arm. Ex. 2 at 2, ¶ 10. She notes that the report of a fall is contradicted by the absence of mention of a fall in the same record elsewhere (the history section). See Ex. 3 at 10. Witness statements she has offered (her own plus that of her daughter, Kim Hill)

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<sup>&</sup>lt;sup>3</sup> Petitioner initiated the case as a *pro se* litigant and filed some exhibits. After counsel's appearance, more complete records were filed, but exhibit numbering erroneously started over, without accounting for the previously-filed materials. *See generally* ECF No. 18 (containing exhibits filed in July 2021). I refer herein to exhibits based on counsel's designations rather than what preceded his appearance, except where otherwise noted.

similarly maintain that Petitioner's right shoulder injury occurred in relation to the flu vaccine rather than an accident, and deny any fall occurred. See, e.g., Declaration of Kim Hill, dated Jan. 3, 2022, filed as Ex. 7 (ECF No. 24-1) at 2. And Petitioner herself later submitted a "statement of disagreement" with this medical record to Russellville Hospital (although it was prepared and offered after this case had been initiated). See "Statement of Disagreement," dated Feb. 22, 2021 (Ex. 3 at 7) ("I said I didn't fall which is noted in the nurse notes that I deny injury and Dr. Bridgewater agreed to nurse notes . . . I received a flu vaccine and two hours later my arm popped and wasn't doing anything"). Regardless, the ER visit records make no mention of Petitioner's receipt of the flu vaccine earlier that day (other than to report that she was up to date for the vaccine). Id. at 9.

Four days later, on September 14, 2020, Petitioner followed up at Russellville Orthopedic Center to see Dr. Lloyd Dyas (who had treated her in the past) for her arm fracture and shoulder pain. Ex 4 at 252. She now included in her history recitation both the fact of the September 10<sup>th</sup> vaccination plus her assertion of a painful right shoulder "pop," with pain since that time. *Id.* Petitioner was diagnosed with a closed fracture of the proximal end of the right humerus with an unspecified fracture morphology. *Id.* at 253. Dr. Dyas recommended conservative treatment, which included the use of a sling, and instructed Petitioner return in three weeks for a follow up appointment. *Id.* at 253.

On the very next day (September 15, 2020), Ms. Hill contacted the Petitioner's primary care physician's office to report that Petitioner had received a flu vaccine the week before, but that a few hours later "she bent over and fractured her humerus." Ex. 6 at 202. Ms. Hill also questioned whether the Petitioner should be checked for Guillain-Barré syndrome (a recognized vaccine-associated injury), although treater notes reacting to this inquiry expressed skepticism. *Id.* ("GUILLAN [sic] BARRE DOESN'T CAUSE FRACTURES?") (emphasis in original).

Petitioner herself saw her primary care physician on September 21, 2020. Ex. 6 at 199–200. She also now reported that she had received a flu vaccine on September 10, 2020, and later that afternoon, she heard a pop and her hand went numb, but when she sought emergency treatment, she was told that she had a fracture. *Id.* This record did not provide an explanation for how the vaccination might have led to the audible pop, although Petitioner did at this time deny recent arm trauma, including falling. *Id.* at 199. Her primary care physician's assessment was a closed fracture of the anatomical neck of the right humerus. *Id.* at 200.

The following month, Petitioner followed up with Dr. Dyas, at which time she reported ongoing and excruciating pain and a limited range of motion in her injured shoulder. Ex. 4 at 261. Dr. Dyas, however, assessed Petitioner as healing well despite her complaints, and she received instructions to follow up with him in four weeks. *Id.* at 262. She returned to Dr. Dyas on November 20, 2020, noting that she was still experiencing pain in her right arm and shoulder and struggling

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with her range of motion, although he again noted her progress in healing. Ex. 4 at 264. Throughout the October-December timeframe, Petitioner also saw her primary care physician, but made no mention of shoulder pain issues. Ex. 6 at 191–98. And she saw Dr. Dyas at the end of 2020, but mainly for a chronic pain management check involving many different issues rather than specific to the injury alleged. Ex. 4 at 268–71.

Petitioner's next medical record relevant to this claim comes from late February 2021—at which time over five months had passed since the vaccination event in question (and this case was now pending as well). On February 22, 2021, Petitioner again returned to Dr. Dyas for a follow-up appointment. Ex 4 at 272–75. Dr. Dyas noted that Petitioner was displaying signs of acromioclavicular arthritis with subacromial and subclavicular spur formation, and diagnosed her with impingement syndrome with rotator cuff tendinopathy. *Id.* at 275. Dr. Dyas recommended right shoulder surgery and Petitioner agreed. *Id.* 

A few weeks later, on March 4, 2021, Petitioner underwent a surgical procedure to repair her right rotator cuff, along with a Mumford procedure (distal clavicle resection), subacromial decompression, bioinductive implant, and debridement. Ex. 4 at 280–81. She was experiencing pain thereafter, and advised that she would need to complete physical therapy. *Id.* at 290–92. She began physical therapy in mid-March 2021, which she represents was painful and also caused radiating pain elsewhere in her arm. Ex. 2 at 4, ¶ 14. Petitioner had a post-operative visit with Dr. Dyas in April 2021, at which time she reported ongoing pain. *Id.* at 298–99. It was recommended that she continue physical therapy, and also engage in at-home exercises. *Id.* at 299.

### **II.** Expert Reports

A. *Petitioner's Expert – Raymond Dahl, M.D.* 

Dr. Dahl is an orthopedic surgeon, and he offered a single written report. Report, dated Dec. 6, 2022, filed as Ex. 9 (ECF No. 34-1) ("Dahl Rep.").

Dr. Dahl received a Bachelor of Science degree from Augusta State University in Augusta, Georgia in 1993. *Curriculum Vitae*, filed as Ex. 10 on Dec. 13, 2022 (ECF No. 34-2) ("Dahl CV") at 1. He received his medical degree from the West Virginia School of Osteopathic Medicine in Lewisburg, West Virginia. *Id.* He completed an internship followed by his residency in Orthopedic Surgery at Pinnacle Health System in Harrisburg, PA. *Id.* Dr. Dahl is board certified in Orthopedic Surgery by the American Osteopathic Academy of Orthopedic Surgeons. *Id.*; Dahl Rep. at 1. He is licensed to practice medicine in Pennsylvania and is an owner/partner in the Orthopedic Institute of Pennsylvania and has been since 2003. *Id.* Dr. Dahl is an instructor to orthopedic residents at Pinnacle Health System. Dahl CV at 1. He is also affiliated with several Osteopathic/Orthopedic organizations. *Id.* 

The first section of Dr. Dahl's report summarizes Petitioner's post-vaccination medical history. *See* Dahl Rep. at 1–4, 7. He then provided capsule citations to a number of items of literature, although for the most part they simply go to the veracity of SIRVA as a vaccination-related injury. *Id.* at 4–10.

Petitioner, Dr. Dahl maintained, had experienced a "right proximal humerus fracture" within hours of her receipt of the flu vaccine. Dahl Rep. at 7. But he deemed the injury to have occurred "without any trauma," and thus no fall or comparable accident—despite what the immediate contemporary treatment records suggest. *Id.* Rather, he accepted Petitioner's contention that she "heard a pop" in her shoulder and then felt pain, without a preceding fall or other accident. *Id.* 

This injury, Dr. Dahl opined, was the result of Petitioner's receipt of the flu vaccine. Dahl Rep. at 8. Although there is a conclusory character to this opinion overall, Dr. Dahl also noted some specific bases for his determination. In particular, he proposed that the "inflammatory reaction" to vaccination had "compromis[ed] the integrity of the skeletal components of the shoulder." *Id.* He later characterized the causal chain as the vaccine (due to "[i]nadvertent overpenetration") leading to a "prolonged inflammatory response in friable osteoporotic bone resulting in humeral head edema," which in turn encouraged bone weakening then the fracture. *Id.* at 10.

This occurred, Dr. Dahl surmised, as a result of the understood mechanism for SIRVA. Dahl Rep. at 8. While many other symptoms (pain, decreased range of motion, bursitis, weakness, etc.) were commonly associated with SIRVA, "rarely fracture" was also possible. *Id.* at 9. Also significant was the absence of any pre-vaccination symptoms, and the close temporal association between vaccination and onset. *Id.* But Dr. Dahl referenced no single literature item discussing the possibility of a misapplied vaccination causing localized inflammation that could also, and in a short timeframe, lead to a bone fracture. Rather, he invoked his own personal clinical expertise in orthopedic surgery, plus Petitioner's medical record and witness statements. *Id.* at 10.

## B. Respondent's Expert – Geoffrey D. Abrams, M.D.

Dr. Abrams, a board-certified orthopedic surgeon, prepared one written report for Respondent, opining therein that Petitioner cannot establish a causation-in-fact claim based on the record. Report, dated Mar. 12, 2023, filed as Ex. A (ECF No. 39-1) ("Abrams Rep.").

Dr. Abrams received a Bachelor of Arts in Human Biology with a concentration in Neuroscience from Stanford University in 2001. *Curriculum Vitae*, filed as Ex. B on May 1, 2023 (ECF No. 39-2) ("Abrams CV") at 1. He received his medical degree from the University of California, San Diego. Abrams CV at 1. He completed a surgical internship at Stanford University in 2008. *Id.* Dr. Abrams completed his residency at Stanford University Hospital and Clinics in 2012, and a fellowship at Rush University Medical Center in 2013. *Id.* Dr. Abrams is board

certified in Orthopedic Surgery, with a subspeciality in Orthopedic Sports Medicine. *Id.*; Abrams Rep. at 1. He is licensed to practice medicine in Illinois and California and is a California Fluoroscopy Supervisor and Operator. Abrams CV at 2. He holds academic appointments at the Stanford University School of Medicine and the Veterans Administration Hospital of Palo Alto. *Id.* at 1; Abrams Rep. at 1. He serves as Team Physician for several professional and collegiate sports teams in the San Francisco Bay Area. *Id.* Dr. Abrams also serves or has previously served on numerous national and international professional orthopedic surgery organization committees. *Id.* 

Dr. Abrams summarized the pertinent medical facts, before turning to the specifics of Petitioner's claim. Abrams Rep. at 2–5. He began by opining that, based on his own expertise as a physician and "from a biomechanical standpoint," it was "not possible for a vaccine administration to cause an acute humerus fracture"—full stop. *Id.* at 5. In so asserting, Dr. Abrams noted that the diameter of a typical vaccine administration needle would simply be too small to penetrate the humerus bone to the degree necessary for the bone to fracture (comparing the needle to larger drill bits used to perform surgical repairs, which *themselves* are incapable of fracturing bone). *Id.* In addition, his own literature search identified no published reports of SIRVA-associated fractures, and he had himself never experienced this occurring in the context of "my clinical experience in treating hundreds of fractures." *Id.* Rather, it was more likely caused by a fall or other accident (and Dr. Abrams deemed the photo offered by Petitioner, which showed shoulder bruising, to be likely consistent with that cause). *Id.* at 6; ECF No. 1-5.

Next, Dr. Abrams addressed the specific mechanism proposed by Dr. Dahl for Petitioner's injury, deeming it flawed. Abrams Rep. at 6. Assuming the vaccine had been administered in Petitioner's right arm, any inflammation related to the event would take "years or decades to exert its clinical effects." *Id.* Literature relevant to the impact of inflammatory bone conditions caused by medication showed that although there could in some cases be an increased risk of fracture due to bone loss or osteoporosis, it would take many years to manifest (and also was not a particularly high risk possibility in any event). *Id.*; S. Abtahi, et al., *Biological Disease-Modifying Antirheumatic Drugs and Osteoporotic Fracture Risk in Patients with Rheumatoid Arthritis: A Danish Cohort Study*, 135 Am. J. Med. 879 (2022), filed as Ex. A-5 (ECF No. 39-7, at 885-86 (no evidence that specific drugs used in treatment of rheumatoid arthritis increase risk of fracture; timeframe for risk measured over years, rather than in days or months). The pathological processes relevant to an immune-mediated condition leading to a heightened risk for fracture could simply not occur in the short timeframe in which Petitioner reported her post-vaccination fracture. Abrams Rep. at 6.

Petitioner's actual treatment evidence, moreover, was not consistent with an immunemediated injury caused by a vaccination, Dr. Abrams argued. He noted, for example, that in connection with Petitioner's March 2021 surgery, the surgeon had placed a "suture anchor (which requires fixation to bone)"—something supporting the conclusion that the bone was in fact "not severely osteoporotic." Abrams Rep. at 6. At the same time, the record revealed that (a) Petitioner had a history of falls consistent with the fall reported in the ER records from the day of vaccination, and (b) other evidence suggested overuse or abuse of pain and anxiety medication, which Dr. Abrams speculated could have had some relationship to her September 2020 ER visit. *Id.* at 7. And Petitioner had been experiencing right shoulder pain *prior* to the ER event as well, which placed in context her course leading to surgery in March 2021. *Id.* That history, he added, could reflect preexisting arthritic issues, or even be associated with diabetes. *Id.* at 7–8.

### III. Procedural History

This claim began its life as a *pro se* case, and was thus assigned to a special master even though it asserts a SIRVA claim (and would therefore ordinarily been adjudicated by OSM's "Special Processing Unit"). Counsel, however, appeared on Petitioner's behalf in mid-2021, and then the Petition was reassigned to me in August 2021. Respondent thereafter raised issues with the claim's viability, leading to some tentative (but unsuccessful) efforts at settlement. Eventually, Respondent filed in June 2022 a Rule 4(c) Report formally challenging the propriety of entitlement, the parties filed competing expert reports, and earlier this year I set a schedule for briefs on the matter.

### IV. Parties' Arguments

Respondent's Motion

Respondent maintains that Petitioner cannot meet the elements for any form of claim—Table or non-Table. With respect to the former, he argues that there is a question as to whether the vaccination at issue was even administered in her right shoulder, the situs of her complaints. Mot. at 9. But even if this matter is decided in Petitioner's favor, she also cannot satisfy the other claim elements. The record shows, for example, that Petitioner had long-standing preexisting right shoulder issues, or other comorbidities that could explain her post-vaccination symptoms. *Id.* at 9–10. More significantly, Petitioner's initial injury was a right, upper-arm bone fracture likely due to a fall—*not* a misapplied vaccine. *Id.* at 9–10.

Petitioner also cannot meet the requirements for a non-Table claim under the Federal Circuit's test set forth in *Althen v. Sec'y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Mot. at 10–14. Petitioner's causation theory, as offered by Dr. Dahl—that her "fracture was caused by a bone-weakening immune response" to vaccination—is wholly unreliable and speculative. *Id.* at 12. Rather, it relies on the SIRVA template, adding in the fact of fracture since the record unquestionably shows that to have been Petitioner's primary initial complaint. *Id.* Petitioner cannot also show the flu vaccine "did cause" an injury, as her theory lacks record support (for example, there is no evidence from the record that Petitioner had experienced bone density

loss post-vaccination). *Id.* at 12–13. And the timeframe prong is also unmet, since the theory of an exaggerated immune response leading to the fracture has not been shown to be consistent with the short timeframe (less than twelve hours) in which Petitioner's injury occurred post-vaccination; rather, inflammation causing bone weaking could take years to manifest. *Id.* 

### Petitioner's Opposition

Petitioner characterizes her injury as a "unique situation"—in which she did in fact experience a SIRVA, followed by the fracture established by the record—but that "spontaneous fractures can be triggered based on the immune response" to the vaccine. Opp. at 1. First, she emphasizes the evidence supporting a Table SIRVA—she received a vaccine likely in her right shoulder, and that she felt pain within the Table onset period (albeit after hearing a "pop"—which is not commonly, if ever, associated with a SIRVA). *Id.* at 13, 16–17. Thereafter, she experienced shoulder pain concurrent with her fracture issues. *Id.* at 14–15. Later, the findings of adhesive capsulitis are consistent with what SIRVA claimants experience. *Id.* at 18. Petitioner denies vehemently that she experienced a pre-onset fall, referencing witness statements on the subject. *Id.* at 15–16, 17. And her preexisting shoulder pain complaints do not relate to her post-vaccination issues. *Id.* at 19. The fracture was also arguably related to the SIRVA, Petitioner continues, noting Dr. Dahl's opinion in support (although Petitioner seems to implicitly maintain that the Table elements could be met even if the fracture were deemed unrelated). *Id.* at 18.

The record also supports, in Petitioner's estimation, a causation-in-fact claim—meaning the case should proceed even if the facts were not deemed to support a Table SIRVA. Opp. at 19–20. This aspect of her argument, however, does seem to rely on a finding that the fracture was caused by vaccination (since Dr. Dahl in particular has opined that the over-penetration of the vaccine needle led to it "coming into contact with friable osteoporotic bone.") *Id.* at 20–21. However, Petitioner equally maintains that this version of the claim as well could succeed even if the fracture were deemed only to be coincidental. *Id.* at 21.

From a procedural/evidentiary standpoint, Petitioner emphasizes that she has offered an expert report plus cited sufficient evidence to make out a *prima facie* SIRVA claim, regardless of the question of the fracture. The claim should therefore be allowed to "advance to a decision on entitlement after an entitlement hearing." Opp. at 2. She argues that too many fact issues, "unsuitable for motions practice," exist to justify summary dismissal at this juncture. *Id.* at 13, 21.

### Reply

Beyond reiterating prior arguments, Respondent's short reply mainly addresses Petitioner's arguments about the procedural propriety of dismissal. He notes that (as of June 2023, when the Reply was filed) the case had existed for more than two years, giving Petitioner ample time to

substantiate the claim. Reply at 1. In addition, Respondent first raised issues with the claim in the fall of 2021, and filed his Rule 4(c) Report in June 2022—meaning Petitioner understood the objections to the claim well before dismissal was requested. Id. at 1-2. Petitioner had also seemingly acquiesced to a ruling on the record, without objecting that certain fact matters remained undeveloped and that required a live hearing. Id. at 2. The record as it stood, Respondent argued, established reasonable grounds for dismissal. Id. at 2.

#### V. **Applicable Legal Standards**

#### A. Petitioner's Overall Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that she suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); see also Moberly v. Sec'y of Health & Hum. Servs., 592 F.3d 1315, 1321 (Fed. Cir. 2010); Capizzano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006).<sup>4</sup> SIRVA claims are defined by the Table, and Petitioner does maintain she can meet the Table elements for such a claim (although she also proposes that a non-Table claim is viable).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance" of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly, 592 F.3d at 1322 n.2; see also Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." Moberly, 592 F.3d at 1321 (quoting Shyface v. Sec'y of Health & Hum. Servs., 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); Pafford v. Sec'y of Health & Hum. Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

504728, at \*7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

<sup>&</sup>lt;sup>4</sup> Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. Hanlon v. Sec'y of Health & Hum. Servs., 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. Guillory v. Sec'y of Health & Hum. Servs., 59 Fed. Cl. 121, 124 (2003), aff'd 104 F. App'x. 712 (Fed. Cir. 2004); see also Spooner v. Sec'y of Health & Hum. Servs., No. 13-159V, 2014 WL

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility... in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)); *see also Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at \*4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed*, No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the

petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at \*17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd* 

mem., 503 F. Appx. 952 (Fed. Cir. 2013); Koehn v. Sec'y of Health & Hum. Servs., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), mot. for rev. den'd (Fed. Cl. Dec. 3, 2013), aff'd, 773 F.3d 1239 (Fed. Cir. 2014).

## B. Legal Standards Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Hum. Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at \*2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at \*20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also* 

Murphy v. Sec'y of Health & Hum. Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992), cert. den'd, Murphy v. Sullivan, 506 U.S. 974 (1992) (citing United States v. United States Gypsum Co., 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at \*19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." Sanchez, 2013 WL 1880825, at \*3 (citing Blutstein v. Sec'y of Health & Hum. Servs., No. 90–2808V, 1998 WL 408611, at \*5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. La Londe v. Sec'y of Health & Hum. Servs., 110 Fed. Cl. 184, 203–04 (2013), aff'd, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. Burns, 3 F.3d at 417.

# C. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the

factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

(1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing Daubert, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs.*, 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g., Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at \*17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations");

see also Porter v. Sec'y of Health & Hum. Servs., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

### D. Standards for Ruling on the Record

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); see also Hooker v. Sec'y of Health & Hum. Servs., No. 02-472V, 2016 WL 3456435, at \*21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. Hovey v. Sec'y of Health & Hum. Servs., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); Burns, 3 F.3d at 417; Murphy v. Sec'y of Health & Hum. Servs., No. 90-882V, 1991 WL 71500, at \*2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

### **ANALYSIS**

### I. Petitioner Cannot Successfully Establish a Table SIRVA

In many cases, identification of the injury alleged is critical to resolution of the claim. *Broekelschen*, 618 F.3d at 1346. Here, determining the injury is important—both to assess if the claim could be viable as a causation-in-fact claim, but also because the success of a Table SIRVA claim depends in part on whether the injury meets the defined criteria. *See* 42 C.F.R. § 100.3(b)(10). Accordingly, a threshold matter to resolve is whether Petitioner's injury was "more likely than not" a SIRVA.

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). The criteria establishing a SIRVA under the accompanying "qualifications and aids to interpretation" ("QAI") are as follows:

SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury

to the musculoskeletal structures of the shoulder (such as tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

- (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
- (ii) Pain occurs within the specified time frame;
- (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
- (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

### 42 C.F.R. § 100.3(c)(10) (2017).

The record evidence in this case strongly preponderates *against* the conclusion that Petitioner experienced a SIRVA. Rather, Petitioner likely experienced a bone fracture—something that is not congruent with a SIRVA at all. There is insufficient evidence of treater views defining her injury as SIRVA-related, whereas ample and consistent records classify the injury as a fracture. And none of the indicia of a SIRVA are established from the immediate record (primarily pain by itself, with potential restrictions to range of motion). The fact that Petitioner later had surgery on her shoulder in March 2021, or that the kind of *incidental* findings common in SIRVA cases were made in connection therewith (*i.e.*, impingement, rotator cuff tears, or tendinopathy), does not corroborate the SIRVA (any more than those findings would inherently rebut a SIRVA). *Lang v. Sec'y of Health & Hum. Servs.*, No. 17-995V, 2020 WL 7873272, at \*13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (noting that evidence of preexisting or subclinical degenerative damage to the shoulder is often found concurrent with SIRVA, in the course of imaging and treatment).

The "bottom line" is that Petitioner's injury is a fracture—not a SIRVA. And I can reach this determination without even factoring in the likely *cause* of the fracture itself (and that issue is addressed below). Otherwise, Petitioner can offer no citation to decisions in which a comparable

injury was deemed consistent with a SIRVA. No Table claim can be successfully established given this record.<sup>5</sup>

In ruling as I do, I acknowledge that a successful SIRVA claim *could involve* evidence that a SIRVA indirectly resulted in an accident that produced secondary injury—comparable to how syncope injuries after vaccination can result in more damaging physical accidents (that in turn become the primary basis for damages in a case). A claimant might well be able to prove that the pain caused by an improperly-administered vaccine was so severe that she fell down, for example, or experienced some other kind of accident resulting in secondary harm. But such a case would need proof that the claimant's immediate post-vaccination issue was clearly pain attributable to the vaccination. Here, contemporaneous record evidence does not preponderantly establish this occurred. (Of course, Petitioner denies she fell in the first place—and therefore is not attempting to establish the fracture as secondary, in the manner I am outlining).<sup>6</sup>

#### II. No Causation Claim is Cognizable Based on the Facts of This Case

It is not uncommon for the same facts relevant to an alleged vaccine injury to be the basis for both a Table and non-Table claim, such that the latter can be viable even if the former is not. Indeed, unsuccessful Table claims are not usually dismissed in their entirety even if it is determined that one or more Table elements cannot be met, since in many cases it is conceivable that a causation-in-fact claim might still be tenable.

Nevertheless, once it is determined that the evidence does not support a Table version of a claim, proving entitlement becomes more difficult (although the preponderant burden of proof is consistent) under a causation in fact analysis. Fantini v. Sec'y of Health & Hum. Servs., No. 15-1332V, 2022 WL 1760730, at \*22 (Fed. Cl. Spec. Mstr. May 2, 2022) (". . . Program claimants cannot "piggyback" on the Table requirements when attempting to prove a non-Table claim."); Greene v. Sec'y of Health & Hum. Servs., No. 11-631V, 2018 WL 3238611, at \*9 (Fed. Cl. Spec. Mstr. May 7, 2018) (noting that an expert's opinion on the timing issue of a brachial neuritis claim relied on conclusory determinations that the "Table time periods were not that far off the time

<sup>&</sup>lt;sup>5</sup> Admittedly, the Table onset element is met, since Petitioner's injury and pain began within a day of vaccination.

<sup>&</sup>lt;sup>6</sup> Even if Petitioner had admitted the fall had occurred, but attributed it as a secondary response to SIRVA, the record evidence does not seem to preponderantly support such a sequence of events. Petitioner's initial visit to the ER, and statements made to treaters at that time, deserve weight over Petitioner's subsequent denials (which were mostly, although not exclusively, prepared in connection with or after the claim's filing). She did not report pain preceding the fall. And even if a factual question existed as to whether the fracture itself was the actual or immediate cause of her pain, as opposed to vaccine administration, the Table element requiring exclusion of any "other condition or abnormality is present that would explain the patient's symptoms" cannot be met, since the fracture is exactly such an explanatory "condition or abnormality." Thus, the plain evidence of the fracture would still defeat a Table SIRVA.

period in question (something Program law says is not permitted)"). Claimants must support each *Althen* prong with sufficient preponderant evidence.

This record does not permit the conclusion that Petitioner experienced a vaccine-related injury. Rather, it is more likely than not that there is simply a temporal association between her fracture (whatever its cause) and vaccination. It is *highly* unlikely the fracture was caused by the vaccine she experienced, and none of the *Althen* prongs are satisfied otherwise.

First, Petitioner has not preponderantly demonstrated that a vaccination *could cause* a bone fracture. Dr. Dahl's opinion that a vaccine could cause inflammation sufficient to weaken a bone (and in a short timeframe as well) was unreliable and unsupported by sufficient independent medical or scientific evidence. By contrast, Dr. Abrams persuasively rebutted that opinion, and his views were more credibly set forth and established to be consistent with what is understood about how SIRVA functions. I am permitted as special master to weigh competing expert opinions, and here I deem Respondent's expert to have more persuasively carried the day on the theory presented.

Second, the record is unsupportive of the conclusion that Petitioner's fracture was likely vaccine-caused. As noted above, the record establishes Petitioner experienced a fracture (whatever its cause). A fracture is not likely to be vaccine-caused, and Petitioner has not shown that the record suggests the vaccination had anything more than a temporal relationship to her injury. Indeed, Dr. Abrams's observations about the incapacity of a vaccine needle to even penetrate a bone, along with his highlighting of evidence from Petitioner's surgical procedure suggestive that her bone density was not in fact a likely concern, also indirectly undermine the inflammation-bone loss theory as actually occurring under the circumstances reflected in the medical record. Also, the record does not preponderantly establish treaters embracing a vaccine association with the fracture, nor can it be shown that Petitioner experienced an immediate increase in inflammation the same day as vaccination sufficient to weaken her bone and cause it to fracture.

Finally, the timeframe in which Petitioner's injury occurred post-vaccination has not been shown to be medically acceptable. Based on Dr. Dahl's theory, inflammation associated with the vaccination was the source of harm to Petitioner's humerus bone, permitting its fracture. But as Dr. Abrams established, the timeframe for such a form of immune-mediated harm would take a lengthy period of time to develop—it would not occur within 12 hours of vaccination. Dr. Abrams's contention on this point was especially persuasive, and has not been rebutted by any

the case, however, since Petitioner cannot meet the first *Althen* prong—it is *highly* unlikely the flu vaccine could precipitate a bone fracture, and the record supports that *this* was Petitioner's injury, regardless of how it occurred.

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<sup>&</sup>lt;sup>7</sup> Petitioner hotly disputes that she fell (and thereby caused the fracture in that manner). Although the most immediate treatment record plainly attributes the injury to falling, and is silent as to vaccination as a factor, Petitioner denies wholly the accuracy of this record - although other than gainsaying its truth (and even attempting post-facto to edit it) she has offered no compelling reason to doubt the first record's accuracy. This issue need not be resolved to decide the agent however gives Petitioner connect most the first Although propagait is highly unlikely the fly vaccine could

literature filings from Petitioner showing that the inflammatory process could occur so rapidly. Petitioner also did not demonstrate that the preexisting comorbidities she might have experienced (for example, the arthritis or diabetes that Dr. Abrams proposed as counter-explanations for the injury) were exacerbated sufficiently by the one-time vaccination event to cause a fracture in record time, simply due to introduction of the vaccine.

### III. This Claim was Appropriately Resolved on the Papers

Petitioner's opposition suggests variously that more input (in particular from experts) is required for the claim's resolution, and/or that it is not reasonably or fairly resolved on the papers. These arguments are unpersuasive. At bottom, and as noted above, it is within a special master's discretion to decide how best to resolve a case. One consideration is whether the claimant has been provided a fair opportunity to substantiate the claim—and this is so here. Petitioner was made aware of Respondent's concerns about the claim nearly two years ago, and had ample time to seek expert input or other evidentiary backing. Petitioner had to be aware from the bare medical record itself of the unique facets of this claim. It cannot be said she did not have a reasonable chance to prove the claim. Otherwise, the claim was easily resolvable on the record. The theory for causation was too thin to justify a hearing, the record was limited, and the case most efficiently resolved in the manner I have utilized.

### **CONCLUSION**

Based on the entire record in this case, I find that Petitioner cannot successfully maintain a Table or non-Table claim that her bone fracture was vaccine-caused. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court SHALL ENTER JUDGMENT in accordance with the terms of this Decision.<sup>8</sup>

IT IS SO ORDERED.

/s/ Brian H. Corcoran Brian H. Corcoran Chief Special Master

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<sup>&</sup>lt;sup>8</sup> Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.